IACUC POLICIES, PROCEDURES, and GUIDELINES

REVIEW OF JOINT VA-UK PROTOCOLS

Purpose:
This document establishes policies and procedures for the IACUC review of animal use activities that are primarily located at the Lexington Veterans Affairs Medical Center (Lexington VA) but involve activities requiring review and oversight by the University of Kentucky and the University of Kentucky IACUC (UK IACUC). This SOP does not apply to non-surgical procedures in research animals lasting less than 12 hours.

Background:
Investigators at the Lexington VA have established collaborative relationships with University of Kentucky investigators or share the use of equipment located at the University of Kentucky. These investigators house their animals at the Lexington VA Veterinary Medical Unit (VMU) under animal use protocols reviewed and approved by the Lexington VA Institutional Animal Care and Use Committee (VA IACUC). In pursuing the collaborative arrangements or use of shared equipment, they transport vertebrate animals to facilities under the jurisdiction and oversight of the University of Kentucky and the University of Kentucky IACUC. This requires that the investigator submit and receive approval from both the VA IACUC and the UK IACUC for the animal activities and places the respective IACUCs in the position of possibly reviewing animal activities approved at another Institution.

As stated in NOT-OD-01-017 (February 12, 2001),

“OLAW and APHIS agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement……

If both institutions have full PHS Assurances, they may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be performed. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees. Similarly, an IACUC would want to know about any significant questions or issues raised during a semiannual program inspection by another IACUC of a facility housing a research activity for which that IACUC bears some responsibility or exposure.”

The Lexington VA uses the standard paper-based VA Animal Component of Research Protocol (ACORP) form. The University of Kentucky uses an electronic protocol submission and approval system (e-Sirius%). This document establishes procedures designed to permit each Institution to fulfill their responsibilities and review the appropriate components of a specific vertebrate animal research proposal without posing a greater burden than is necessary upon the investigator or the respective IACUCs.

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Responsibilities:

The Memorandum of Understanding between the University of Kentucky and the Lexington Veterans Affairs Medical Center establishes the requirements for IACUC review, approval, and oversight for protocols involving the resources of both Institutions. The following two criteria require that a Lexington VA investigator obtain review, approval, and oversight by the UK IACUC for an animal activity primarily performed under a protocol approved by the VA IACUC:

1) The animal is housed at the University of Kentucky for greater than 12 hours.

2) Surgical manipulations are performed at the University of Kentucky.

In both of these situations, the investigator is subject to review, approval, and oversight by the UK IACUC and is subject to the rules and regulations of the University of Kentucky. As stated in the Memorandum of Understanding, “The VA IACUC may not grant permission for the use of University resources where approval by the University’s IACUC is required. Similarly, the University’s IACUC may not grant permission for the use of VA resources where approval by the VA IACUC is required.”

Due to ongoing construction at the VMU animal facility a new MOU between the UK and VAMC was established on June 1, 2014. This MOU allows for the transfer of animals to DLAR facilities during the construction period and describes each parties’ responsibilities during this period.

The construction period is expected to be two years at which time animals may be returned to the VMU animal facility and the applicable MOU may be terminated.

Procedures for Joint Protocol Processing

1. Investigators with approved VA ACORPs desiring to add components requiring UK IACUC approval must submit either an amendment/modification or new protocol (which ever the case may be) requests to both the UK IACUC and the VA IACUC. In the case of an amendment, these requests should be submitted simultaneously because approval from both IACUCs is required prior to the initiation of any activities requested in the amendment/protocol. In the case of a new protocol, the VA protocol will be approved first so that the ACORP may be attached to the UK protocol. Investigators planning to submit a joint protocol must first notify the VMU supervisor. The supervisor will initiate the UK IACUC e-Sirius® amendment/protocol. If the UK activity comes in the form of an amendment, then the amendment’s reason/purpose should state “UK/VA joint protocol” followed by the amendment’s identification number. Prior to submission of an amendment/protocol requesting UK IACUC approval of an activity listed in a VA -approved ACORP, an electronic copy of the complete approved VA ACORP (Adobe Acrobat PDF format) is attached by the VA Research Staff to the Title page of the “skeleton” e-Sirius® protocol. VA amendments and modifications are sequentially numbered and attached to the ACORP with the appropriate appendices and approvals associated with each modification. Unlike in the UK e-Sirius® system, the original VA ACORP is not automatically modified to reflect amendments approved after the initial protocol approval. Amendments to VA ACORPs and new VA protocols requiring UK IACUC approval must be submitted via the e-Sirius® protocol system. Investigators must access the system with their log-on and password and complete the unfinished amendment, created by the VMU supervisor in Item 1. This can be done by clicking on the protocol number, selecting and

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completing the pages listed in Item 4, and submitting the amendment to the UK IACUC Office. The amendment/e-Sirius protocol should describe the animal-related activities proposed to be performed at the University of Kentucky. The investigator does not need to complete the entire e-Sirius® protocol form as the attached VA-approved protocol will provide adequate details regarding the other protocol activities at the VA to permit review by the UK IACUC. The following e-Sirius® pages/fields must be included in the amendment/e-Sirius® protocol to permit UK IACUC review and approval:

a. **Experimental Design: Animal Methodology:** Description of the activities proposed to be performed at the University of Kentucky. This section should be limited to only those activities being performed at the University of Kentucky and for which UK IACUC approval is being sought. The activities should be identical to that requested under question #3 of the VA form “Modification of the Animal Component of Research Protocol (ACORP)” if submitted as an amendment.

b. **Species: Animal Usage Location** Where the animals will be held (>12 hours) or be surgically manipulated. This is required to ensure that the site(s) is (are) included in the UK IACUC semiannual facility and program review.

c. **Personnel:** Any personnel not listed on the VA ACORP and involved in the animal activities at the University of Kentucky must be listed.

2. The amendment/e-Sirius® protocol must be submitted by the principal investigator using their e-Sirius® logon and password. The submitted amendment/new protocol will be reviewed by the UK IACUC following standard policies and procedures for all amendments/new protocols using the designated review process. The UK IACUC Office will ensure that the appropriate VA documents have been attached to the e-Sirius® “skeleton” protocol prior to submitting the request for IACUC review and approval via Designated Review. The investigator will receive e-mail communications regarding the UK IACUC review through the e-Sirius® system.

3. The UK IACUC will be responsible for ensuring that the University of Kentucky animal housing and usage sites listed on the protocol are included in the UK semiannual facility and program review.

4. The annual review process for non-USDA covered species is deferred to the VA IACUC.

5. The VMU supervisor must be notified prior to animals being transported to and returned from UK facilities.

References:


2. UK/VA Memorandum of Understanding, 07/31/2009

3. UK/VA Memorandum of Understanding, 06/01/2014

Appendix:

1. UK/VA Memorandum of Understanding, 1/6/2014

Approved and Adopted by the Institutional Animal Care and Use Committee
September 16, 2009

Administratively Revised
October 17, 2012

Administratively Revised
September 17, 2014

Administratively Revised
September 30, 2015

Administratively Revised September 30, 2015
Memorandum of Understanding Between
The Lexington Veterans Administration Medical Center And
The University of Kentucky

Date 1 June 2014

WHEREAS, The University of Kentucky (University or UK) and the Lexington Veterans Administration Medical Center (VA) (collectively, Institutions or Parties) each have an Institutional Animal Care and Use Committee (IACUC) to review research protocols and perform other functions as provided by applicable laws and regulations for research projects being carried out at their respective sites; and

WHEREAS, due to the unusually close physical proximity of the Parties' facilities, the University has researchers who are working on protocols at the VA site and the VA has researchers who are working on protocols at the University; and

WHEREAS, the UK and the VA share a commitment to high quality and ethical care and use of research animals; and

WHEREAS, the University and the VA have agreed to maintain separate accreditation with the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), separate registration with the United States Department of Agriculture (USDA) and separate Public Health Service (PHS) Assurance registration; and

WHEREAS, the VA Veterinary Medical Unit (VMU) animal facility will be rendered unusable for animal housing during the expansion and renovation of the Main Building which is scheduled to begin on or about 15 August 2014 and continue for an anticipated 2 years;

WHEREAS, the Division of Laboratory Animal Resources (DLAR) of the University is an AAALAC accredited facility and has the capability to house the animals presently housed in the VA VMU animal facility;

NOW, THEREFORE, in consideration of the mutual promises set forth herein, and for other good and valuable consideration, the University and the VA agree as follows for the period of time during which the VA animal facility is unavailable:

1. Nothing contained in this agreement is intended to relieve either Institution of any of its duties or obligations, but sets forth the Parties' understanding and processes to ensure effective oversight of animal care involving both facilities and to avoid unneeded duplication of effort. Unless otherwise agreed in writing, each party shall be responsible for its own expenses in carrying out its duties hereunder.

2. Each Institution's IACUC shall be guided by:
   a. Animal Welfare Act and all applicable federal and state statutes and regulations relating to animals.
c. "Guide for the Care and Use of Laboratory Animals" published by the National Academy of Sciences as amended and revised.
d. The "Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching" published by the Federation of Animal Science Societies as amended and revised.
e. Public Health Service Policy on Humane Care and Use of Laboratory Animals.
f. The VA is governed by VHA Handbook 1200.07.

3. Each Institution shall be responsible for its own semi-annual program and facility evaluations. The UK IACUC shall invite all members of the VA IACUC to participate in facility inspections being conducted by the UK IACUC where animal use under a VA Animal Component of Research Proposal (ACORP) occurs. VA IACUC members shall not count toward the minimum number of UK IACUC members required for a semiannual inspection.

4. To the extent applicable to one institution's research protocols being conducted at the other's site, each Institution agrees to make the relevant sections of the following reports available upon request for review by the Chairperson of the other Institution's IACUC or by another IACUC representative designated by the Chairperson.
   a. USDA inspection reports
   b. Semi-annual program evaluations.
   c. Semi-annual facility inspection reports.
   d. AAALAC accreditation correspondence.
   e. Personnel training records.
   f. Occupational Health enrollment records.
   g. Records of noncompliance investigations.

5. The University and the VA shall each provide a copy of the relevant sections of its semi-annual program review and facility inspection self-assessment to the other Institution's IACUC for review. Each Institution shall retain the right to independently inspect any area where vertebrate animals are used on an approved protocol at that Institution. The Institutions will cooperate in all such inspection requests.

6. For all animal research protocols, including amendments, funded by any source and administered through UK, the UK e-Sirius® animal use protocol form shall be used and the UK IACUC shall be the IACUC of record. The UK IACUC shall be responsible for the review and approval of the animal use protocol and for all amendments/modifications to the approved protocol. The UK IACUC shall ensure that all personnel have completed the required UK training prior to listing on an approved animal use protocol.

7. For all animal research protocols, including amendments, which involve VA funding or funding that is administered through the VA, the VA IACUC shall be the IACUC of record. The VA IACUC shall be responsible for the review and approval of the ACORP and for all amendments/modifications to the approved ACORP. The VA IACUC shall ensure that all personnel listed on the ACORP have completed all the required VA training requirements.
   a. The VA IACUC shall additionally ensure that all personnel listed on the ACORP have completed all of the training requirements of the UK IACUC as a component of the review and approval of all protocols and amendments/modifications.
b. The VA shall ensure that the approved VA ACORP and associated subcommittee forms, along with the formal approval notifications are loaded into the UK e-Sirius® system as a component of the protocol approval process. Personnel contact information must be completed for each approved ACORP loaded into the UK e-Sirius® system database.

8. The University shall accept the VA Occupational Health and Safety Program (OHSP) Occupational Health and Medical Evaluation program for individuals performing work at the University and not otherwise covered under the University program. Treatment and care for work related injuries to personnel enrolled under the VA OHSP program shall remain the responsibility of the VA.

9. The University shall bill the VA a single, monthly per diem fee based on daily animal populations and the existing approved DLAR per diem rates. The VA will pay this fee, monthly, through an annual contractual agreement with the University. This contractual agreement will have three option years on it.

10. The parties agree that the DLAR of the University will decide upon optimal food, caging, and husbandry practices for animals housed in University animal facilities, and that the University will be responsible for the provision of adequate veterinary care. The University will retain authority for decisions related to such care, including emergency euthanasia as may deemed appropriate by University personnel. The VA agrees to abide by applicable University Standard Operating Procedures solely relating to animals brought to and housed at the University.

11. All animal purchases made with VA funding must be placed through the VA Research Office. The VA Research Office shall ensure that the DLAR business office is notified and has approved the order prior to placing the order with the vendor. Cage cards for all animal orders will be generated by the DLAR business office.

12. In the case of a serious accident, animal welfare concern, or incident of non-compliance involving a VA ACORP with animals housed at UK, the initial responsibility for investigation and fact finding shall reside with the UK IACUC. The UK IACUC shall notify the chair of the VA IACUC within 24 hours of initiating an investigation regarding a credible animal welfare concern. The primary lead IACUC for the investigation shall be mutually determined.

a. In cases where the incident involves a deviation or noncompliance with the approved VA ACORP the VA IACUC may become the IACUC of record responsible for the final investigation, conclusions, corrective actions, and reporting of the incident.

b. In deviations and noncompliant activities not directly related to the approved protocol, the UK IACUC would most likely become the IACUC of record.

In all cases involving a VA ACORP, the IACUC of record shall provide the other IACUC with documentation of the findings of the investigation, the conclusions and determinations of the IACUC, and the corrective actions required by the IACUC and the Institutional Official (IO) if applicable.

13. In cases where the IACUC Chairpersons or their representatives cannot agree upon
the establishment of a primary investigating IACUC a joint subcommittee for investigation shall be established. This subcommittee shall consist of a minimum of 2 members from each IACUC and shall, as a representative of both IACUC's, be responsible for the investigation, documentation of findings, and recommended corrective actions, if any. The joint subcommittee's report shall be presented to both IACUC's for discussion and final resolution and recommendations to the respective IOs.

14. This Agreement will be in effect for up to five years and continue unless the Agreement is terminated by one or both of the Institutions by written notice from the IO. Termination shall occur six months after written notification by either Institution.

15. The Agreement and any amendments may not be extended, renewed, or otherwise amended except in writing and signed by the IO of both Institutions.

16. This Agreement will be governed by and construed in accordance with Federal laws of the United States and where not inconsistent with the laws of the State of Kentucky.

This Agreement will become effective upon the date of the last signature below.

Agreed to and Approved by:

Pedro L. Vera, PhD
Associate Chief of Staff for Research and Development
Veterans Administration Medical Center

Emma Metcalf, MSN, RN
Director
Veterans Administration Medical Center

Harold F. Stills, DVM
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